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| EXAMINER |
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| FOX, D | |
| ART UNIT | PAPER NUMBER |

1638
DATE MAILED:

28
08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application N.

08/903,944

Applicant(s)

Smith et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/1/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-45, 47-106 and 108-118 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 6-37, 38-45, 47-106 and 108-118 is/are rejected.
- ☒ Claim(s) 4-5 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 101, which omitted the following phrases (which had been added by the amendment of 13 April 1999):

In parts (b) through (d) of claim 101, after "embryogenic callus", the phrase --containing embryos-- should have been present.

Errors also appear in claim 102, part (b), where "culturing reddish epidermal" should have been replaced with --subculturing embryogenic-- as amended by the amendment of 13 April 1999.

The amendment of 1 June 2001 has overcome the objection to claim 103 regarding errors, and has overcome the rejection of claims 39 and 103, parts (b) and (e) only, as being indefinite under 35 USC 112, second paragraph.

The supplemental declaration of 1 June 2001 has been received and entered.

Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, 108-112, 114-115 and 117-118 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the production of transgenic poinsettia via particle bombardment, does not reasonably provide enablement for claims broadly drawn to any other method of producing transgenic poinsettia or the plants produced therefrom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

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Claims 39-45, 47-72, 99, 103, 106, 109, and 118 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 103, and dependents, are indefinite in their recitation of "culturing callus produced on medium X on medium Y" as it is confusing whether the callus is being cultured in two media simultaneously, or whether callus originally produced on a first medium is now being transferred to a second medium. If the latter were intended, the following amendments would obviate this rejection:

In claims 39 and 103, part (g), replace "culturing" with --subculturing-- and replace the second recitation of "on" with --to--.

Claims 1-3, 97, 101, 104, 113 and 116 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Preil et al taken with Nataraja, in light of Lee et al, as stated in the last office action.

Claims 1-3, 6-8, 11-41, 44-45, 47-106 and 108-118 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al taken with Preil (1994) and Nataraja, in light of Lee et al, as stated in the last office action.

Claims 4, 5, 9, 10, 42 and 43 remain free of the prior art, given the failure of the prior art to teach or suggest the use of high concentrations of mannitol for the somatic embryogenesis-mediated propagation of poinsettia, as stated in the last office action.

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Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicant's arguments filed 1 June 2001, insofar as they pertain to the remaining rejections, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection regarding non-exemplified means of poinsettia transformation is improper, given the failure of *Agrobacterium rhizogenes* results to be predictive of those using *Agrobacterium tumefaciens*, and the amendment of the claims to delete "electroporation".

The Examiner maintains that Applicants' assertions as to the predictability of *Agrobacterium tumefaciens*-mediated transformation of poinsettia are not deemed probative. See also Applicants' traversal of the Examiner's past rejection of the claims under 35 USC 103 as being obvious over a combination of references involving *Agrobacterium* (see, e.g., pages 12-13 of the amendment of 28 November 2000, which allude to the unpredictability inherent in applying *Agrobacterium* to poinsettia).

With regard to electroporation, some of the method claims do not recite any particular transformation methods, and so read on electroporation as well as polycation-mediated transformation, both of which require wall-less protoplasts, wherein techniques for whole

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poinsettia regeneration therefrom were not available to the skilled artisan at the time of the invention, as stated in the office action of 7 July 1999, page 3, bottom paragraph.

Applicants urge that the art rejections are improper, given the failure of Preil et al to suggest the incorporation of casein hydrolysate, the lack of motivation to combine the casein hydrolysate used for zygotic embryo culture as taught by Nataraja et al, the failure of either reference to teach the particular nitrogen compounds in an embryo induction medium, an osmotic pressure increasing agent in a developmental medium, or abscisic acid in a maturation medium; and the failure of Miki et al to address these deficiencies.

The Examiner maintains that the use of casein hydrolysate as a tissue culture medium addition is well known, and that Nataraja et al teach its use in an embryo culture medium for poinsettia. Although Nataraja et al teach the use of zygotic rather than somatic embryos, one of ordinary skill in the art would have recognized that the extract would have worked equally well for each type of embryo. Regarding the other medium additions, the Examiner maintains that the use of the particularly claimed nitrogen sources in tissue culture media is well known, as is the use of abscisic acid. Furthermore, not all of the claims are drawn to the use of these compounds, either singly or in combination with each other or with other exemplified tissue culture medium additions. Regarding osmotic agent, the Examiner maintains that any carbohydrate or salt addition will change the osmotic pressure to some degree, when compared to the osmotic pressure of distilled water. Thus, Miki et al are not required to supplement the combination of Preil et al and Nataraja et al with regard to tissue culture components or methods.

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Applicants' evidence of unexpected results, namely the genotype-independent obtention of whole, optionally transformed poinsettia plants following micropropagation, relies upon the use of high levels of a particular osmoticum and high levels of particular nitrogen sources, optionally in combination with microprojectile-mediated transformation. In contrast, the rejected claims are broadly drawn to any osmoticum at any concentration, any nitrogen source or conventional nitrogen sources at conventional concentrations, or any transformation method. See *In re Lindner* and *In re Grasselli* cited previously.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 6, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~188~~ 1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written in dark ink.